DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 4 1993

Re: Lovenox®
Docket No. 93E-0214

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

#464

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,692,435, filed by Choay S.A. under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Lovenox®, the human drug product claimed by the patent.

The total length of the regulatory review period for Lovenox® is 1,777 days. Of this time, 1,322 days occurred during the testing phase and 455 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: May 19, 1988.

   FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was May 19, 1988.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: December 31, 1991.

   The applicant claims December 31, 1993 as the NDA effective date "to determine the applicable regulatory review period", but claims July 26, 1991 as the "initially submitted" date in its actual calculation of the length of the extention. FDA records indicate that the new drug application (NDA 20-164), submitted on July 26, 1991, was incomplete. The FDA refused to file this incomplete application and notified the applicant of this fact by letter dated September 20, 1991. The completed NDA was then submitted on December 31, 1991, which is properly considered to be the NDA initially submitted date.

3. The date the application was approved: March 29, 1993.

FDA has verified the applicant's claim that NDA 20-164 was approved on March 29, 1993.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Steven J. Lee
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